Product Labeling & Patient Safety

PROPOSED REVISION

Based on the principle that all medicine should be labeled with accurate and useful information that has been independently verified.

REQUIREMENTS CONCERNING OPERATION OF CULTIVATION FACILITY OR FACILITY FOR THE PRODUCTION OF EDIBLE MARIJUANA PRODUCTS OR MARIJUANA-INFUSED PRODUCTS

Sec. 70. **OK AS IS**

Sec. 71. *1. A cultivation facility must disclose in writing with each lot of usable marijuana provided to a medical marijuana dispensary,* TO A FACILITY FOR PRODUCTION OF EMPs/MIPs, OR TO ANOTHER CULTIVATION FACILITY:

(a) **OK AS IS**

(b) The SAFETY CERTIFICATION AND THE name of the independent testing laboratory which performed the required quality assurance tests and the results of the required quality assurance tests for the ~~lot~~ BATCH of usable marijuana ~~or marijuana products~~.

2. **OK AS IS**

3. THE USABLE MARIJUANA MUST BE IN A SEALED, TAMPER-EVIDENT PACKAGE OR CONTAINER LABELED WITH THE FOLLOWING INFORMATION:

(a) BATCH NUMBER;

(b) NAME AND REGISTRATION NUMBER OF THE CULTIVATION FACILITY; and

(c) WEIGHT OF THE PRODUCT.

Sec. 72. *1.* **OK AS IS**

2. **OK AS IS**

3. EACH CULTIVATION FACILITY SHALL ENSURE THAT ANALYTICAL TESTING AGENTS OF AN INDEPENDENT, THIRD-PARTY ACCREDITED LABORATORY HAVE FULL, UNIMPEDED ACCESS TO TAKE RANDOM SAMPLES FROM A HARVEST BATCH.

4. RENUMBER PREVIOUS #3 – **OK AS IS**

PACKAGING AND LABELING OF MEDICAL MARIJUANA

Sec. 73. *1. Any product containing marijuana must be packaged* IN PLAIN, OPAQUE, SEALED, TAMPER-EVIDENT CONTAINERS WITHOUT DEPICTIONS OF THE PRODUCT, CARTOONS, OR IMAGES OTHER THAN LOGO. EDIBLE EMPs/MIPs SHALL NOT BEAR A REASONABLE RESEMBLANCE TO ANY PRODUCT AVAILABLE FOR CONSUMPTION AS A COMMERCIALLY AVAILABLE CANDY ~~in child resistant packaging in accordance with Title 16 C.F.R. § 1700 of the Poison Prevention Packaging Act or use standards specified in subsection 2 or 3 of this section.~~

2. **OK AS IS**

3. **OK AS IS**

4. **OK AS IS**

Sec. 74. **OK AS IS** – HOWEVER, SECTION SEEMS POTENTIALLY CONFUSING AND UNNECESSARY

Sec. 75. **OK AS IS** – HOWEVER, SECTION SEEMS POTENTIALLY CONFUSING AND UNNECESSARY

Sec. 76. **DELETE**

Sec. 77. *A ~~cultivation facility or~~ facility for the production of edible marijuana products or marijuana-infused products shall label each marijuana product before it sells the product to a dispensary and shall securely affix to the package a label that includes,* AT A MINIMUM ~~*without limitation*~~*, in legible English:*

1. The name of the medical marijuana establishment and the registration certificate number of the establishment THAT PRODUCED THE PRODUCT*;*

2. The ~~lot number~~ BATCH NUMBER, SEQUENTIAL SERIAL NUMBER, AND BAR CODE WHEN USED, TO IDENTIFY THE BATCH ASSOCIATED WITH CULTIVATION AND PROCESSING;

3. The date of harvest;

4. The date of final testing and packaging of the product;

5. A SAFETY CERTIFICATION FROM INDEPENDENT TESTING FACILITY WHICH REPORTS:

(a) ALL ACTIVE INGREDIENTS THAT CONSTITUTE AT LEAST ONE (1) WT. % OF THE MARIJUANA IN THE PRODUCT, TO ALWAYS INCLUDE:

(I) DELTA 9-TETRAHYDROCANNABINOL (THC);

(II) CANNABIDIOL (CBD)

(b) A PASS/FAIL RATING BASED ON A MICROBIOLOGICAL ANALYSIS THAT WAS COMPLETED IMMEDIATELY PRIOR TO FINAL PACKAGING;

(c) A PASS/FAIL RATING BASED ON A CHEMICAL RESIDUE ANALYSIS THAT WAS COMPLETED IMMEDIATELY PRIOR TO FINAL PACKAGING; MEDICAL MARIJUANA DISPENSARY AND

(d) NAME AND PLACE OF BUSINESS OF AN INDEPENDENT SAFETY TESTING FACILITY AND DATE FINAL ANALYSES WERE COMPLETED. ~~*The cannabinoid profile and potency levels and terpinoid profile as determined by the independent testing laboratory;*~~

6. If the product is perishable, the expiration date;

7. The NET WEIGHT IN OUNCES AND GRAMS, OR VOLUME AS APPROPRIATE; ~~*quantity of the marijuana being sold*~~*;*

8. Recommended serving size and the number of servings contained within the unit, including total milligrams of active cannabinoids and terpinoids as provided by the independent testing laboratory that tested the product;
(9) Warnings that state: "Caution: When eaten or swallowed, the intoxicating effects of this drug may be delayed by two or more hours.";
(10) If a marijuana extract was added to the product, disclosure of the type of extraction process and any solvent, gas, or other chemical used in the extraction process, or any other compound added to the extract;
(11) Warnings that state: "This product has intoxicating effects and may be habit forming"; and
(12) Statement that: "This product may be unlawful outside of the State of Nevada".

LABELING OF USEABLE MEDICAL MARIJUANA

Sec. 78. A CULTIVATION FACILITY, A FACILITY FOR PRODUCTION OF EMPs/MIPs, OR a *medical marijuana dispensary must affix to each container or package containing usable marijuana sold at retail a label which must include, without limitation:*

1. THE NAME OF THE MEDICAL MARIJUANA ESTABLISHMENT AND THE REGISTRATION CERTIFICATE NUMBER OF THE ESTABLISHMENT THAT PACKAGED THE PRODUCT;
2. THE LOT NUMBER BATCH NUMBER, SEQUENTIAL SERIAL NUMBER, AND BAR CODE WHEN USED, TO IDENTIFY THE BATCH ASSOCIATED WITH CULTIVATION AND PROCESSING;
3. THE DATE OF HARVEST;
4. THE DATE OF PACKAGING OF THE PRODUCT;
5. A SAFETY CERTIFICATION FROM AN INDEPENDENT SAFETY TESTING FACILITY WHICH REPORTS:
   (a) ALL ACTIVE INGREDIENTS THAT CONSTITUTE AT LEAST ONE (1) WT. % OF THE MARIJUANA IN THE PRODUCT, TO ALWAYS INCLUDE:
      (i.) DELTA 9-TETRAHYDROCANNABINOL (THC);
      (ii.) CANNABIDIOL (CBD)
   (b) A PASS/FAIL RATING BASED ON A MICROBIOLOGICAL ANALYSIS THAT WAS COMPLETED IMMEDIATELY PRIOR TO FINAL PACKAGING;
   (c) A PASS/FAIL RATING BASED ON A CHEMICAL RESIDUE ANALYSIS THAT WAS COMPLETED IMMEDIATELY PRIOR TO FINAL PACKAGING; MEDICAL MARIJUANA DISPENSARY AND
   (d) NAME AND PLACE OF BUSINESS OF AN INDEPENDENT TESTING FACILITY AND DATE FINAL ANALYSES WERE COMPLETED.

(6) Warnings that state: "This product has intoxicating effects and may be habit forming";
(7) Statement that "This product may be unlawful outside of the State of Nevada"; ~~*and*~~
~~*(i) Date of harvest.*~~

LABELING OF EDIBLE MARIJUANA AND MARIJUANA-INFUSED PRODUCTS

Sec. 79. *1. A medical marijuana dispensary must affix to each container or package containing edible marijuana or marijuana-infused products sold at retail a label which must include, without limitation:*

(a) The business or trade name and the registration certificate number AND TELEPHONE NUMBER *of the* ~~*facility for the production of edible marijuana*~~

~~*products or marijuana-infused products of the facility that produced, processed, and*~~ *medical marijuana dispensary THAT sold the marijuana-*~~*infused product*~~*;*

~~*(b) Lot numbers of all base marijuana used to create the product;*~~

~~*(c) Batch number of the edible or infused product;*~~

~~*(d) Date dispensed and quantity dispensed, in net weight in ounces and grams, or volume, as appropriate;*~~

(e) Name and registry identification card number of the qualified patient, and the name of the designated caregiver, if any;

~~*(f) Name and address of the medical marijuana dispensary;*~~

(g) Date ~~*manufactured*~~ SALE

(h) If the product is perishable, a prominently printed expiration date based on the recommended conditions of use and store of the facility for the production of edible marijuana products or marijuana-infused products, which is not later than the expiration date determined by the producer and that can be read and understood by an average person;

(i) A UNIQUE SERIAL NUMBER AND/OR BAR CODE THAT WILL MATCH THE PRODUCT WITH A MEDICAL MARIJUANA DISPENSARY'S BATCH SO AS TO FACILITATE ANY WARNINGS OR RECALLS;

(*j*) THE DATE OF DISPENSING THE MARIJUANA;

(*k*) THE QUANTITY OF MARIJUANA DISPENSED;

(*l*) THE NAME OF THE CERTIFYING PHYSICIAN;

(*o*) SUCH DIRECTIONS FOR THE TYPE OF CANNABIS AND FOR ITS USE AS MAY BE INCLUDED IN THE PHYSICIAN'S WRITTEN CERTIFICATION OR OTHERWISE PROVIDED BY THE PHYSICIAN.

2. **NEW SAMPLE LABEL NEEDED**

3. A medical marijuana dispensary must provide with all edible marijuana and marijuana-infused products sold at retail accompanying material that discloses all pesticides applied to the marijuana plants and growing medium during production of the base marijuana used to create the extract added to the infused product and the type of extraction method, including any solvents, gases, or other chemicals or compounds used to produce or that are added to the extract, and contains the following warnings:

(a) "There may be health risks associated with consumption of this product";

(b) "This product is infused with marijuana or active compounds of marijuana";

(c) "Should not be used by women who are pregnant or breast feeding";

(d) "For use only by the person named on the label of the dispensed product. Keep out of reach of children"

(e) "Products containing marijuana can impair concentration, coordination, and judgment. Do not operate a vehicle or machinery under the influence of this drug"; and

(f) "Caution: When eaten or swallowed, the intoxicating effects of this drug may be delayed by two or more hours."

4. The font used on all accompanying material must be no smaller than 12 point in size and may not use italics.

Sec. 101 *1. A facility for the production of edible marijuana products or marijuana-infused products may only use the methods, equipment, solvents, gases and mediums set forth in this section when creating marijuana extracts.* PRODUCT LABEL MUST INCLUDE STATEMENT THAT DISCLOSES THE TYPE OF EXTRACTION METHOD, INCLUDING ANY SOLVENTS, GASES, OR OTHER CHEMICALS OR

COMPOUNDS USED TO PRODUCE OR THAT ARE ADDED TO THE EXTRACT.

2.— 7. **OK AS IS**

Sec. 114 *1.* **OK AS IS**
2. **DELETE**
3. **OK AS IS**

Sec. 115. *Each cultivation facility, facility for the production of edible marijuana products or marijuana-infused products, and medical marijuana dispensary shall, to assure that a medical marijuana product meets applicable standards of identity, strength, quality and purity at the time of use, ensure that the product ~~bears an expiration date determined by appropriate laboratory-based stability testing.~~* IS LABELED WITH INFORMATION NECESSARY TO COMPLY WITH STATE OR LOCAL LABELING REQUIREMENTS FOR SIMILAR PRODUCTS NOT CONTAINING MARIJUANA, INCLUDING BUT NOT LIMITED TO THE NEVADA FOOD REGULATIONS GOVERNING THE SANITATION OF FOOD ESTABLISHMENTS (NRS CHAPTER 439, AS AMENDED); AND THE NEVADA ADMINISTRATIVE CODE.

Sec. 120. *An independent testing laboratory shall not handle, test or analyze marijuana unless:*
1. The laboratory has been issued a medical marijuana establishment registration certificate;
2. The laboratory is independent from all other persons involved in the medical marijuana industry in Nevada; and
3. No person with a direct or indirect interest in the laboratory has a direct or indirect financial interest in ANOTHER NEVADA MEDICAL MARIJUANA ESTABLISHMENT.

~~(a) A medical marijuana dispensary;~~
~~(b) A facility for the production of edible marijuana products or marijuana-infused products;~~
~~(c) A cultivation facility;~~
~~(d) A physician who provides or has provided written documentation for the issuance of registry identification cards; or~~
~~(e) Any other entity that may benefit from the production, manufacture, dispensing, sale, purchase or use of marijuana.~~

Sec. 121. 1. *Immediately before ~~manufacturing~~* THE FINAL PACKAGING OF *any marijuana product or ~~packaging~~ raw marijuana for sale to a medical marijuana dispensary, a cultivation facility shall segregate all harvested marijuana into homogenized batches. ~~and select a random sample from each batch for testing by an independent testing laboratory.~~ Each cultivation facility must designate a person responsible for segregating all harvested marijuana into homogenized batches pursuant to this subsection. That person:*

(a) Must receive training provided by the Division in the proper methods of ~~selecting~~ PREPARING *a ~~random,~~ homogenized sample for testing;*
(b) Is responsible for filing an attestation with the Division as to the manner in which each random, homogenized ~~sample is selected~~ BATCH WAS PREPARED *for testing;* AND
(c) WILL PROVIDE ANALYTICAL TESTING AGENTS OF AN INDEPENDENT,

THIRD-PARTY ACCREDITED LABORATORY FULL, UNIMPEDED ACCESS TO TAKE RANDOM SAMPLES FROM THE BATCH.

Sec. 125. *1. The Division shall establish an Independent Laboratory Advisory Committee ~~not to exceed 7 total members~~ comprised of:*

(a) A representative from each independent testing laboratory in this state;

(b) **OK AS IS**

(c) **OK AS IS**

2. **OK AS IS**

Sec. 133. *The provisions of this regulation governing labeling and testing of marijuana products apply to all marijuana products, including, without limitation, ~~pre-rolls~~* DRIED FLOWERS & LEAVES (SINGLE STRAIN OR BLENDS), CONCENTRATES (SINGLE STRAIN OR BLENDED), CAPSULES, TINCTURES, OILS, LIQUIDS, GELS, LOTIONS, EDIBLE FOOD PRODUCTS, DRINKS, PRE-ROLLED CANNABIS CIGARETTES AND CARTRIDGES FOR "E-CIG" VAPOR PRODUCTS.

Sec. 145. A DISPENSARY SHALL ADOPT, DOCUMENT, AND IMPLEMENT POLICIES AND PROCEDURES REGARDING PATIENT EDUCATION AND SUPPORT, INCLUDING

1. AVAILABILITY OF DIFFERENT CHEMOTYPES OF MARIJUANA AND THE PURPORTED EFFECTS OF THE DIFFERENT CHEMOTYPES;

2. INFORMATION ABOUT THE PURPORTED EFFECTIVENESS OF VARIOUS METHODS AND FORMS OF MEDICAL MARIJUANA ADMINISTRATION;

3. METHOD FOR TRACKING THE EFFECTS ON A QUALIFYING PATIENT OF DIFFERENT CHEMOTYPES AND FORMS OF MEDICAL MARIJUANA.

Sec. 146. ALL MARIJUANA AND MARIJUANA PRODUCTS SHALL BE PROCESSED PACKAGED AND LABELED ACCORDING TO THE US FOOD AND DRUG ADMINISTRATION'S "CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKAGING, LABELING, AND/OR HOLDING OPERATIONS FOR DIETARY SUPPLEMENTS" RULE.

NECESSARY ADDITIONS TO DEFINITION SECTION

TO SUPPORT PROPOSED REVISIONS

DEFINITIONS

Sec. 2. "**ACTIVE INGREDIENTS ANALYSIS**" MEANS A REPORT ISSUED BY AN INDEPENDENT LABORATORY ON A BATCH BASIS THAT SHOWS ALL ACTIVE INGREDIENTS THAT CONSTITUTE AT LEAST ONE (1) PERCENT OF THE MARIJUANA, TO ALWAYS INCLUDE DELTA 9-TETRAHYDROCANNABINOL (THC) AND CANNABIDIOL (CBD).

Sec. 3. *"Batch" means a specific ~~lot of marijuana grown from one or more seeds or cuttings that are planted and harvested at the same time.~~* HARVEST OF MARIJUANA THAT IS IDENTIFIABLE BY A BATCH NUMBER, EVERY PORTION OR PACKAGE OF WHICH IS UNIFORM WITHIN RECOGNIZED TOLERANCES FOR THE FACTORS THAT WERE SUBJECT TO AN INDEPENDENT LABORATORY TEST AND THAT APPEAR IN THE LABELING

Sec. 4. *"Batch number" means ~~a unique numeric or alphanumeric identifier assigned to a batch by a medical marijuana establishment when the batch is planted.~~* ANY DISTINCT GROUP OF NUMBERS, LETTERS, OR SYMBOLS, OR ANY COMBINATION THEREOF, ASSIGNED BY A CULTIVATION FACILITY TO A SPECIFIC HARVEST BATCH OR PRODUCTION BATCH OF MEDICAL MARIJUANA OR MARIJUANA-INFUSED PRODUCT.

"**CONTAINER**" MEANS THE SEALED PACKAGE IN WHICH MEDICAL MARIJUANA OR A MEDICAL MARIJUANA PRODUCT IS PLACED FOR SALE TO QUALIFYING PATIENTS OR PRIMARY CAREGIVERS AND THAT HAS BEEN LABELED ACCORDING TO THE REQUIREMENTS SET FORTH IN SECTION 77 AND 78.

Sec. 12. "*Lot" means either:*

1. The flowers from one or more marijuana plants of the same strain, in a quantity that weighs ~~five~~ THREE (3) *pounds or less; or*

2. The leaves or other plant matter from one or more marijuana plants, other than full female flowers, in a quantity that weighs ~~fifteen~~ TEN (10) pounds or less.

"**MARIJUANA-INFUSED PRODUCT**" MEANS A TOPICAL FORMULATION, TINCTURE, BEVERAGE, EDIBLE SUBSTANCE, OR SIMILAR PRODUCT CONTAINING ANY USABLE MARIJUANA THAT IS INTENDED FOR HUMAN CONSUMPTION IN A MANNER OTHER THAN SMOKE INHALATION.

"**SAFETY CERTIFICATION**" MEANS THE RESULTS OF AN ACTIVE INGREDIENT ANALYSIS, A MICROBIOLOGICAL CONTAMINANTS ANALYSIS, AND A PESTICIDE CHEMICAL RESIDUE ANALYSIS WHICH HAVE BEEN COMPLETED ON A BATCH BASIS BY AN INDEPENDENT TESTING LABORATORY.